

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claims 1-203 (cancelled)

Claim 204 (new) A method comprising the steps of:

- (a) choosing one or more EPO dosage regimens, wherein said one or more EPO dosage regimens maintains at least a serum EPO concentration above a predose level for about 5 to about 30 days;

- (b) using a pharmacokinetic/pharmacodynamic model to determine the pharmacodynamic profile of said one or more EPO dosage regimens; and

- (c) selecting said one or more EPO dosage regimens that provide said desired pharmacodynamic response based on said pharmacodynamic profile.

Claim 205 (new) The method of claim 204, wherein said serum EPO concentration is sufficient to increase production of red blood cells.

Claim 206 (new) The method of claim 205, wherein said serum EPO concentration is sufficient to maintain increased red blood cell production for at least about one week.

Claim 207 (new) The method of claim 205, wherein said serum EPO concentration is sufficient to maintain increased red blood cell production for at least about two weeks.

Claim 208 (new) The method of claim 204, wherein said EPO dosing regimen comprises administering EPO about once a week.

Claim 209 (new) The method of claim 208, wherein said once a week EPO dosing regimen comprises administering a dose of EPO in the range of about 300 IU/kg to about 2400 IU/kg.

Claim 210 (new) The method of claim 208, wherein said once a week EPO dosing regimen comprises administering a dose of EPO in the range of about 30,000 IU to about 54,000 IU.

Claim 211 (new) The method of claim 204, wherein said EPO dosing regimen comprises administering a dose of EPO about once every two weeks.

Claim 212 (new) The method of claim 211, wherein said once every two weeks EPO dosing regimen comprises administering a dose of EPO in the range of about 900 IU/kg to about 1200 IU/kg.

Claim 213 (new) The method of claim 204, wherein said EPO dosing regimen comprises administering EPO about once every ten days.

Claim 214 (new) The method of claim 213, wherein said once every ten days EPO dosing regimen comprises administering a dose of EPO of about 900 IU/kg.

Claim 215 (new) The method of claim 204, 206, 207, 208, 211, or 213, wherein said EPO dosing regimen comprises administering EPO selected from the group consisting of epoietin alpha and darbepoietin alpha.

Claim 216 (new) The method of claim 204, wherein said EPO dosing regimen comprises administering EPO selected from the group consisting of novel erythropoiesis stimulating protein (NESP), human erythropoietin analog, and erythropoietin omega.

Claim 217 (new) The method of claim 204, wherein said EPO dosing regimen comprises administering proteins having EPO biological activity.

Claim 218 (new) The method of claim 217, wherein said proteins having EPO biological activity are selected from the group consisting of erythropoietin analogs, erythropoietin isoforms, and renal erythropoietin.

Claim 219 (new) The method of claim 204, wherein said EPO dosing regimen comprises administering EPO derived from the group consisting of naturally occurring EPO, recombinant EPO, and synthetic EPO.

Claim 220 (new) The method of claim 204, wherein said patient has anemia.

Claim 221 (new) The method of claim 220, wherein said anemia comprises EPO concentration related anemia.

Claim 222 (new) The method of claim 221, wherein said anemia is selected from the group consisting of end-stage renal failure, renal failure related anemia, and dialysis related anemia.

Claim 223 (new) The method of claim 220, wherein said anemia comprises cancer chemotherapy related anemia.

Claim 224 (new) The method of claim 220, wherein said anemia comprises AIDS drug therapy related anemia.

Claim 225 (new) The method of claim 220, wherein said anemia comprises drug related anemia.

Claim 226 (new) The method of claim 225, wherein said drug is selected from the group consisting of cisplatin and carboplatin.

Claim 227 (new) The method of claim 225, wherein said drug is zidovudine.

Claim 228 (new) The method of claim 204, wherein said patient is undergoing blood donation.

Claim 229 (new) The method of claim 204, wherein said patient has received a bone marrow transplant.

Claim 230 (new) The method of claim 204, wherein said patient has rheumatoid arthritis.

Claim 231 (new) The method of claim 204, wherein said EPO dosing regimen comprises administering EPO via a route selected from the group consisting of intravenous administration, subcutaneous administration, and parental administration.

Claim 232 (new) The method of claim 204, wherein said EPO dosing regimen comprises administering EPO having a modified glycosylation pattern.

Claim 233 (new) The method of claim 232, wherein said EPO having a modified glycosylation pattern comprises darbepoietin alpha.

Claim 234 (new) A method comprising the steps of:

- (a) selecting one or more desired pharmacodynamic responses;
- (b) using a pharmacokinetic /pharmacodynamic model to determine EPO dosage regimens that provides said desired one or more pharmacodynamic responses; and
- (c) selecting the one or more EPO dosage regimens that provide said desired pharmacodynamic responses, wherein said one or more EPO dosage regimens maintains at least a serum EPO concentration above a predose level for about 5 to about 30 days.

Claim 235 (new) The method of claim 234, wherein said serum EPO concentration is sufficient to increase production of red blood cells.

Claim 236 (new) The method of claim 235, wherein said serum EPO concentration is sufficient to maintain increased red blood cell production for at least about one week.

Claim 237 (new) The method of claim 235, wherein said serum EPO concentration is sufficient to maintain increased red blood cell production for at least about two weeks.

Claim 238 (new) The method of claim 234, wherein said EPO dosing regimen comprises administering EPO about once a week.

Claim 239 (new) The method of claim 238, wherein said once a week EPO dosing regimen comprises administering a dose of EPO in the range of about 300 IU/kg to about 2400 IU/kg.

Claim 240 (new) The method of claim 238, wherein said once a week EPO dosing regimen comprises administering a dose of EPO in the range of about 30,000 IU to about 54,000 IU.

Claim 241 (new) The method of claim 234, wherein said EPO dosing regimen comprises administering a dose of EPO about once every two weeks.

Claim 242 (new) The method of claim 241, wherein said once every two weeks EPO dosing regimen comprises administering a dose of EPO in the range of about 900 IU/kg to about 1200 IU/kg.

Claim 243 (new) The method of claim 234, wherein said EPO dosing regimen comprises administering EPO about once every ten days.

Claim 244 (new) The method of claim 243, wherein said once every ten days EPO dosing regimen comprises administering a dose of EPO of about 900 IU/kg.

Claim 245 (new) The method of claim 234, 236, 237, 238, 241, or 243, wherein said EPO dosing regimen comprises administering EPO selected from the group consisting of epoietin alpha and darbepoietin alpha.

Claim 246 (new) The method of claim 234, wherein said EPO dosing regimen comprises administering EPO selected from the group consisting of novel erythropoiesis stimulating protein (NESP), human erythropoietin analog, and erythropoietin omega.

Claim 247 (new) The method of claim 234, wherein said EPO dosing regimen comprises administering proteins having EPO biological activity.

Claim 248 (new) The method of claim 247, wherein said proteins having EPO biological activity are selected from the group consisting of erythropoietin analogs, erythropoietin isoforms, and renal erythropoietin.

Claim 249 (new) The method of claim 234, wherein said EPO dosing regimen comprises administering EPO derived from the group consisting of naturally occurring EPO, recombinant EPO, and synthetic EPO.

Claim 250 (new) The method of claim 234, wherein said patient has anemia.

Claim 251 (new) The method of claim 250, wherein said anemia comprises EPO concentration related anemia.

Claim 252 (new) The method of claim 251, wherein said anemia is selected from the group consisting of end-stage renal failure, renal failure related anemia, and dialysis related anemia.

Claim 253 (new) The method of claim 250, wherein said anemia comprises cancer chemotherapy related anemia.

Claim 254 (new) The method of claim 250, wherein said anemia comprises AIDS drug therapy related anemia.

Claim 255 (new) The method of claim 250, wherein said anemia comprises drug related anemia.

Claim 256 (new) The method of claim 255, wherein said drug is selected from the group consisting of cisplatin and carboplatin.

Claim 257 (new) The method of claim 255, wherein said drug is zidovudine.

Claim 258 (new) The method of claim 234, wherein said patient is undergoing blood donation.

Claim 259 (new) The method of claim 234, wherein said patient has received a bone marrow transplant.

Claim 260 (new) The method of claim 234, wherein said patient has rheumatoid arthritis.

Claim 261 (new) The method of claim 234, wherein said EPO dosing regimen comprises administering EPO via a route selected from the group consisting of intravenous administration, subcutaneous administration, and parental administration.

Claim 262 (new) The method of claim 234, wherein said EPO dosing regimen comprises administering EPO having a modified glycosylation pattern.

Claim 263 (new) The method of claim 262, wherein said EPO having a modified glycosylation pattern comprises darbepoietin alpha.

Claim 264 (new) A method comprising the steps of:

- (a) choosing one or more EPO dosage regimens, wherein said one or more EPO dosage regimens maintains at least a serum EPO concentration above a predose level for about 5 to about 30 days;

- (b) using a pharmacokinetic /pharmacodynamic model to determine the pharmacokinetic profile of said one or more EPO dosage regimens; and

- (c) selecting the one or more EPO dosage regimens that provide said desired pharmacokinetic response based on said pharmacokinetic profile.

Claim 265 (new) The method of claim 264, wherein said serum EPO concentration is sufficient to increase production of red blood cells.

Claim 266 (new) The method of claim 265, wherein said serum EPO concentration is sufficient to maintain increased red blood cell production for at least about one week.

Claim 267 (new) The method of claim 265, wherein said serum EPO concentration is sufficient to maintain increased red blood cell production for at least about two weeks.

Claim 268 (new) The method of claim 264, wherein said EPO dosing regimen comprises administering EPO about once a week.

Claim 269 (new) The method of claim 268, wherein said once a week EPO dosing regimen comprises administering a dose of EPO in the range of about 300 IU/kg to about 2400 IU/kg.

Claim 270 (new) The method of claim 268, wherein said once a week EPO dosing regimen comprises administering a dose of EPO in the range of about 30,000 IU to about 54,000 IU.

Claim 271 (new) The method of claim 264, wherein said EPO dosing regimen comprises administering a dose of EPO about once every two weeks.

Claim 272 (new) The method of claim 271, wherein said once every two weeks EPO dosing regimen comprises administering a dose of EPO in the range of about 900 IU/kg to about 1200 IU/kg.

Claim 273 (new) The method of claim 264, wherein said EPO dosing regimen comprises administering EPO about once every ten days.

Claim 274 (new) The method of claim 273, wherein said once every ten days EPO dosing regimen comprises administering a dose of EPO of about 900 IU/kg.

Claim 275 (new) The method of claim 264, 266, 267, 268, 271, or 273, wherein said EPO dosing regimen comprises administering EPO selected from the group consisting of epoietin alpha and darbepoietin alpha.

Claim 276 (new) The method of claim 264, wherein said EPO dosing regimen comprises administering EPO selected from the group consisting of novel erythropoeisis stimulating protein (NESP), human erythropoietin analog, and erythropoietin omega.

Claim 277 (new) The method of claim 264, wherein said EPO dosing regimen comprises administering proteins having EPO biological activity.

Claim 278 (new) The method of claim 277, wherein said proteins having EPO biological activity are selected from the group consisting of erythropoietin analogs, erythropoietin isoforms, and renal erythropoietin.

Claim 279 (new) The method of claim 264, wherein said EPO dosing regimen comprises administering EPO derived from the group consisting of naturally occurring EPO, recombinant EPO, and synthetic EPO.

Claim 280 (new) The method of claim 264, wherein said patient has anemia.

Claim 281 (new) The method of claim 280, wherein said anemia comprises EPO concentration related anemia.

Claim 282 (new) The method of claim 281, wherein said anemia is selected from the group consisting of end-stage renal failure, renal failure related anemia, and dialysis related anemia.

Claim 283 (new) The method of claim 280, wherein said anemia comprises cancer chemotherapy related anemia.

Claim 284 (new) The method of claim 280, wherein said anemia comprises AIDS drug therapy related anemia.

Claim 285 (new) The method of claim 280, wherein said anemia comprises drug related anemia.

Claim 286 (new) The method of claim 285, wherein said drug is selected from the group consisting of cisplatin and carboplatin.

Claim 287 (new) The method of claim 285, wherein said drug is zidovudine.

Claim 288 (new) The method of claim 264, wherein said patient is undergoing blood donation.

Claim 289 (new) The method of claim 264, wherein said patient has received a bone marrow transplant.

Claim 290 (new) The method of claim 264, wherein said patient has rheumatoid arthritis.

Claim 291 (new) The method of claim 264, wherein said EPO dosing regimen comprises administering EPO via a route selected from the group consisting of intravenous administration, subcutaneous administration, and parental administration.

Claim 292 (new) The method of claim 264, wherein said EPO dosing regimen comprises administering EPO having a modified glycosylation pattern.

Claim 293 (new) The method of claim 292, wherein said EPO having a modified glycosylation pattern comprises darbepoietin alpha.

Claim 294 (new) A method comprising the steps of:

- (a) selecting one or more desired pharmacokinetic responses;
- (b) using a pharmacokinetic/pharmacodynamic model to determine EPO dosage regimens that provide said desired one or more pharmacokinetic responses; and
- (c) selecting one or more EPO dosage regimens that provide said desired pharmacokinetic responses, wherein said one or more EPO dosage regimens maintains at least a serum EPO concentration above a predose level for about 5 to about 30 days.

Claim 295 (new) The method of claim 294, wherein said serum EPO concentration is sufficient to increase production of red blood cells.

Claim 296 (new) The method of claim 295, wherein said serum EPO concentration is sufficient to maintain increased red blood cell production for at least about one week.

Claim 297 (new) The method of claim 295, wherein said serum EPO concentration is sufficient to maintain increased red blood cell production for at least about two weeks.

Claim 298 (new) The method of claim 294, wherein said EPO dosing regimen comprises administering EPO about once a week.

Claim 299 (new) The method of claim 298, wherein said once a week EPO dosing regimen comprises administering a dose of EPO in the range of about 300 IU/kg to about 2400 IU/kg.

Claim 300 (new) The method of claim 298, wherein said once a week EPO dosing regimen comprises administering a dose of EPO in the range of about 30,000 IU to about 54,000 IU.

Claim 301 (new) The method of claim 294, wherein said EPO dosing regimen comprises administering a dose of EPO about once every two weeks.

Claim 302 (new) The method of claim 301, wherein said once every two weeks EPO dosing regimen comprises administering a dose of EPO in the range of about 900 IU/kg to about 1200 IU/kg.

Claim 303 (new) The method of claim 294, wherein said EPO dosing regimen comprises administering EPO about once every ten days.

Claim 304 (new) The method of claim 303, wherein said once every ten days EPO dosing regimen comprises administering a dose of EPO of about 900 IU/kg.

Claim 305 (new) The method of claim 294, 296, 297, 298, 301, or 303, wherein said EPO dosing regimen comprises administering EPO selected from the group consisting of epoietin alpha and darbepoietin alpha.

Claim 306 (new) The method of claim 294, wherein said EPO dosing regimen comprises administering EPO selected from the group consisting of novel erythropoiesis stimulating protein (NESP), human erythropoietin analog, and erythropoietin omega.

Claim 307 (new) The method of claim 294, wherein said EPO dosing regimen comprises administering proteins having EPO biological activity.

Claim 308 (new) The method of claim 307, wherein said proteins having EPO biological activity are selected from the group consisting of erythropoietin analogs, erythropoietin isoforms, and renal erythropoietin.

Claim 309 (new) The method of claim 294, wherein said EPO dosing regimen comprises administering EPO derived from the group consisting of naturally occurring EPO, recombinant EPO, and synthetic EPO.

Claim 310 (new) The method of claim 294, wherein said patient has anemia.

Claim 311 (new) The method of claim 310, wherein said anemia comprises EPO concentration related anemia.

Claim 312 (new) The method of claim 311, wherein said anemia is selected from the group consisting of end-stage renal failure, renal failure related anemia, and dialysis related anemia.

Claim 313 (new) The method of claim 310, wherein said anemia comprises cancer chemotherapy related anemia.

Claim 314 (new) The method of claim 310, wherein said anemia comprises AIDS drug therapy related anemia.

Claim 315 (new) The method of claim 310, wherein said anemia comprises drug related anemia.

Claim 316 (new) The method of claim 315, wherein said drug is selected from the group consisting of cisplatin and carboplatin.

Claim 317 (new) The method of claim 315, wherein said drug is zidovudine.

Claim 318 (new) The method of claim 294, wherein said patient is undergoing blood donation.

Claim 319 (new) The method of claim 294, wherein said patient has received a bone marrow transplant.

Claim 320 (new) The method of claim 294, wherein said patient has rheumatoid arthritis.

Claim 321 (new) The method of claim 294, wherein said EPO dosing regimen comprises administering EPO via a route selected from the group consisting of intravenous administration, subcutaneous administration, and parental administration.

Claim 322 (new) The method of claim 294, wherein said EPO dosing regimen comprises administering EPO having a modified glycosylation pattern.

Claim 323 (new) The method of claim 322, wherein said EPO having a modified glycosylation pattern comprises darbepoietin alpha.